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**STATE OF DELAWARE**  
**OFFICE OF CONTROLLED SUBSTANCES**

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<b>PUBLIC MEETING NOTICE:</b>	<b>CONTROLLED SUBSTANCE COMMITTEE</b>
<b>DATE AND TIME:</b>	<b>Wednesday, August 27, 2014 at 9:00 a.m.</b>
<b>PLACE:</b>	<b>Buena Vista Conference Center, Dining Room, First Floor, 661 S. DuPont Highway, New Castle, Delaware 19720</b>
<b>APPROVED:</b>	November 5, 2014

**MEMBERS PRESENT**

Michael Kremer, DMD, Dental Representative, President  
Stephen Ruggles, PA-C, PA Representative  
Art Jankowski, VMD, Veterinary Representative  
Luis Garcia, Jr., DPM, Podiatric Representative, Vice President  
Herb E. Von Goerres, R.Ph., Pharmacy Representative  
Jo Ann M. Baker, MSN, RN, FNP-C, Nursing Representative  
Mark Hanna, Public Representative  
David W. Dryden, R.Ph., J.D., Director Office of Controlled Substances

**MEMBERS ABSENT**

Philip Kim, M.D., Medical Representative  
Alex Zarrow, R.Ph., Pharmacy Representative

**DIVISION STAFF/DEPUTY ATTORNEY GENERAL**

Christine Mast, Administrative Specialist III  
Michelle McCreary, Pharmacy Compliance Officer  
Eileen Kelly, Deputy Attorney General  
David Mangler, Director, Division Professional Regulation  
Kim A Hurley, Court Reporter-Wilcox & Fetzer

**ALSO PRESENT**

R. Hancock, DSP  
Hooshang Shanchsaz, DPS  
Stacey Stewart, DOJ  
Letitia Kanar, AIDHC  
Dale Perkel, AIDHC  
Patrick A Titus M.D.  
Josie Walters  
Paul Shulli  
Don Holst, Walgreens  
Cheryl Hieks  
Doug Gramiak, Young Conaway Public Strategies  
Keith Sokoloff D.O.  
Michael R Perna, Attorney

Richard P. Jaskewich, PA.  
Raphaele Todaro M.D.  
Jeanne Chigiorini, ACSCAN

### **CALL TO ORDER**

Dr. Kremer called the meeting to order at 9:00 am.

### **REVIEW AND APPROVAL OF MINUTES**

A motion was made by Mr. Von Goerres, seconded by Mr. Hanna, to approve the minutes from the April 23, 2014 meeting as presented. The motion was unanimously carried.

A motion was made by Mr. Von Goerres, seconded by Mr. Hanna, to approve the minutes from the June 17, 2014 meeting as amended. The motion was unanimously carried.

### **PRESIDENT'S REPORT**

Dr. Kremer reported that hydrocodone will be moved from Schedule III to Schedule II effective October 6, 2014.

### **UNFINISHED BUSINESS**

#### **Re-Review Dr. Keith Sokoloff Application @9:30 am**

Ms. Kelly called the hearing to order at 10:40 am and provided the committee a brief outline of the previous review and proposal to deny hearing previously held. Mr. Dryden reported that he had verified information with the Maryland DEA and what documents were required for approval. The Maryland DEA (SAC) office was provided all documents required for their approval that were provided to Delaware. Dr. Sokoloff' Maryland Controlled Substance Registration currently has no restrictions and is active. A motion was made by Dr. Garcia, seconded by Mr. Von Goerres, to approve the application on a restricted basis limiting the registration to schedules to IV and V. The motion was unanimously carried.

#### **Review of Consent Agreement Jaine Weiss**

DAG Eileen Kelly requested the Consent Agreement be tabled until the next meeting due to amendments made to the agreement. A motion was made by Mr. Von Goerres, seconded by Dr. Jankowski, to table the review until the next scheduled meeting. The motion was unanimously carried.

### **NEW BUSINESS**

**Review of Hearing Officer Recommendation – Dr. Patrick Titus M.D.:** Ms. Eileen Kelly, Deputy Attorney General asked that all parties presenting testimony to introduce themselves and be sworn for the record. Verbatim testimony was taken by the court reporter. Ms. Kelly read the Hearing Officer Recommendation into the record. Dr. Titus was present and represented by Counsel by Mr. Ligouri. The Department of State was represented by Counsel Stacey Stewart, to present exceptions to the Hearing Officer Recommendation. Ms. Stewart addressed the committee and presented the states written exceptions to the committee. She stated that the recommended discipline was not severe enough and that the committee is requested to consider more stringent discipline up to and including revocation. Mr. Ligouri testified and disputed the request for an increased level of discipline and further stated a reduction in discipline was prudent. Dr. Titus provided testimony to the committee. The committee went into deliberations. Deliberations concluded with a motion made by Dr. Garcia, seconded by Dr. Jankowski, to change the recommended discipline to include one year suspension with three years' probation, educational training in Pain Management, and an independent auditor to conduct random audits at the expense of Dr. Titus. The motion was unanimously carried.

#### **Proposal to Deny Hearing Richard P Jaskewich @ 9:15 am**

The hearing was called to order at 11:04 am. Ms. Eileen Kelly, Deputy Attorney General asked that all parties presenting testimony to introduce themselves and be sworn for the record. Mr.

Jaskewich's attorney, Michael Perna, introduced himself and Mr. Jaskewich as well as a witness for Mr. Jaskewich, Dr. Todaro. The committee introduced themselves for the record. Verbatim testimony was taken by the court reporter. Ms. Kelly stated the purpose of the hearing into the record. Testimony was given by Dr. Todaro, Mr. Jaskewich and Mr. Perna. The committee asked questions of the witnesses and Mr. Jaskewich. The committee proceeded into deliberations. Deliberations concluded a motion was made by Dr. Garcia, seconded by Dr. Kremer, to approve the registration application. The motion was unanimously carried.

Discussion: Proposed Regulations changes for ALL opioids that lack abuse-deterrent:

Mr. David Mangler, Director Division of Professional Regulation, addressed the committee regarding the emergency regulation that was previously approved on an emergency basis will automatically expire. Mr. Mangler discussed the need for further discussion regarding all opioids that lack abuse-deterrent. He has received written and verbal feedback from many stake holders regarding regulation. The committee agreed that more discussion regarding drafting proposed regulation was required. The committee requested for this to be left on the agenda for future discussion.

**DIRECTOR'S REPORT**

Mr. Dryden reported he would be attending the NASCSA meeting October 21-24, 2014 as the Delaware delegate.

**Case/Diversion Review**

Mr. Dryden reported that he and some of the staff were assisting the Delaware State Police with and investigation in Sussex County. The investigation was initiated due to prescriptive items being sold in non-pharmacies.

Mr. Dryden also expressed the confusion with Veterinarians and the 72 hour dispensing law. Mr. Dryden will be sending out another alert to help clear the confusion. Mr. Dryden and Ms. McCreary will also begin focusing on veterinary office inspections to help assist with educating the veterinarians on the dispensing law.

Mr. Dryden stated that Hydrocodone will be changed from Schedule III to Schedule II effective October 6, 2014. Tramadol was changed from prescription only to Schedule IV effective August 18, 2014.

**PMP Review**

Mr. Dryden and Ms. Nettesheim attended the HID, PMP vendor meeting in July.

Mr. Dryden and Ms. Nettesheim are currently working with the University of Delaware to contract them for analysis of PMP data and geo-mapping. Ms. Nettesheim is working to create definitions and report parameters to analyze death data vs. PMP data. NABP, DPR, CHHS and CERN will be meeting in the next few weeks to discuss a business alignment to integrate PMP data directly into CHHS work flow. This would enable CHHS practitioners the ability to access PMP data without leaving their workflow.

PMP Delegate accounts for practice staff were released a few weeks ago. This provides delegated staff access to the PMP to provide support to the practitioner in access the PMP data.

**National Disposal**

Mr. Dryden reported that the next DEA Drug Disposal is scheduled for September 27, 2014, 10 am to 2 pm at various locations across the state.

**Current Event Review**

*Twenty-Five States' Prescription Data Now Linked Through NABP PMP InterConnect*

Supporting state efforts to fight prescription drug abuse, participation in the National Association of Boards of Pharmacy® (NABP®) PMP InterConnect® program continues to grow with 25 prescription monitoring programs (PMPs) now live. With half of the states now sharing PMP data via this secure communication platform, authorized PMP users in those states are able to see a more complete history of patients' controlled substance prescriptions, helping health care providers identify possible misuse or abuse.

#### *New Study Highlights Key Quality Standards for Large-Scale Sterile Compounding*

A new study comparing safety measures used by pharmaceutical manufacturing facilities with those used by compounding facilities highlights the quality standards that are needed by all compounding facilities, including those engaged in large-scale compounding. [Quality Standards for Large-Scale Sterile Compounding Facilities](#) (PDF), authored by Clinical IQ, LLC, and commissioned by [Pew Charitable Trusts](#), provides information about the changes in scope and magnitude of sterile drug compounding from the 1980s to the present. The study also provides information for stakeholders and regulators on important quality standards needed to ensure safety in large-scale compounding facilities, and on Title I of the Drug Quality and Security Act, which establishes the new category of “outsourcing facility” for large-scale compounding operations and requires these entities to be regulated by Food and Drug Administration (FDA).

#### *FDA Detains Hundreds of Packages Containing Illegal Prescription Drugs Bound for US Consumers*

As part of the seventh annual International Internet Week of Action (IIWA), FDA and Customs and Border Protection detained and seized 583 packages of illegal prescription drugs at mailing facilities in Los Angeles, New York, and Chicago. These medications were ordered through rogue online drug sellers and websites. Preliminary findings show that certain drug products from abroad, including insulin, estrogen, bimatoprost, human chorionic gonadotropin, tramadol, tadalafil, and sildenafil citrate, were being shipped to United States consumers, notes an FDA [press release](#). In addition to seizing the packages, FDA notified Internet service providers, domain name registrars, and related organizations that nearly 2,000 websites were selling products in violation of US law.

Known as Operation Pangea VII, the IIWA efforts brought together law enforcement, customs, and regulatory authorities from 111 countries. Worldwide, nearly 20,000 packages containing medications purportedly from Australia, the United Kingdom, New Zealand, and Canada were seized.

#### *Senior Prescription Drug Abuse A Growing Problem, USA Today Reports*

While efforts to curb high rates of prescription drug abuse continue, prescription painkiller abuse and misuse is increasing among seniors. In fact, the number of seniors who were misusing or dependent on prescription pain medications climbed from 132,000 in 2002 to more than 330,000 in 2012, according to a [USA Today report](#). Further, the number of opioid prescriptions written for seniors increased by 20% over five years, as indicated in the report. The article also explored possible causes for the epidemic such as overprescribing and dangerous combinations of drugs such as benzodiazepines and opioid painkillers.

#### *DEA Publishes Final Rules Rescheduling Tramadol to Schedule IV*

The US Drug Enforcement Administration today published its [Final Rule](#) in the Federal Register placing tramadol into Schedule IV effective August 18, 2014. Effective August 18, 2014 all manufacturers will be required to print the designation "C-IV" on every bottle and it is unlawful for commercial containers of tramadol to be distributed without that designation. In addition, all DEA registrants will be required to take an inventory of all tramadol stock in compliance with 21 C.F.R. § 1304.11(d).

*FDA Releases DQSA Compounding Rules and Guidance Documents*

Food and Drug Administration (FDA) has released several policy documents related to compounding as part of the agency's implementation of the Drug Quality and Security Act (DQSA). The documents include:

- Draft [interim guidance](#) (PDF) describing FDA's expectations for compliance with current good manufacturing practice requirements for compounding facilities registered as outsourcing facilities with FDA
- A [proposed rule](#) (PDF) that would revise FDA's current list of drug products that may not be compounded due to withdrawal from the market or because they were found to be unsafe or ineffective
- [Final guidance](#) (PDF) for pharmacies and individuals that intend to compound drugs under Section 503A, including FDA's interim policies and a non-exhaustive list of potential enforcement actions against pharmacies or individuals that compound in violation of the Food, Drug, and Cosmetic Act
- Two *Federal Register* notices that reopen FDA's request for nominations for the bulk drug substances lists for compounding in relation to [Section 503A](#) (PDF) and [Section 503B](#) (PDF) respectively

The draft interim guidance and proposed rule are available for public comment for 60 days, and the dockets are open for the public to nominate bulk drug substances for compounding under section 503A or 503B for 90 days. Additional information is available in a [press release](#) on the FDA website.

*FedEx Indicted Over Role in Delivering Misbranded Prescription Drugs Ordered from Illegal Online Drug Sellers*

Corporation has been indicted by a federal grand jury in San Francisco, CA, in connection with its alleged role in trafficking controlled substances (CS) and misbranded prescription drugs for rogue online drug sellers. The [indictment](#) (PDF) alleges that, as early as 2004, FedEx knew that it was delivering drugs to dealers and addicts. When FedEx couriers expressed concerns over irregular behavior from customers receiving packages from online drug sellers, the company's senior management adopted a procedure allowing packages from "problematic shippers" to be held for pickup at specific stations, rather than delivered to the recipient's address, according to the indictment.

FedEx is also charged with conspiring with two separate online drug sellers: the Chhabra-Smokey Organization and Superior Drugs, indicates a [press release](#) from the United States Attorney's Office for the Northern District of California. In each case, FedEx allegedly conspired to distribute CS and prescription drugs to customers who had no legitimate medical need, and who had invalid prescriptions issued by doctors acting outside the usual course of professional practice.

"Illegal Internet pharmacies rely on illicit Internet shipping and distribution practices. Without intermediaries, the online pharmacies that sell counterfeit and other illegal drugs are limited in the harm they can do to consumers," said Philip J. Walsky, Acting Director, Food and Drug Administration (FDA)'s Office of Criminal Investigations. "The FDA is hopeful that today's action will continue to reinforce the message that the public's health takes priority over a company's profits."

### **FDA Approves New Abuse-Deterrent Opioid Pain Medication**

The FDA has approved Targiniq™ ER, an opioid pain reliever designed to be more resistant to abuse. The drug is an extended-release/long-acting (ER/LA) opioid analgesic for treating pain severe enough to require around-the-clock, long-term opioid treatment, and for which alternative treatment options are inadequate. Targiniq ER is the first to combine naloxone hydrochloride, an overdose reversal drug, and oxycodone, an opioid pain reliever. The naloxone blocks the euphoric effects of oxycodone if the drug is crushed and snorted, or crushed, dissolved, and injected, indicates an FDA [press release](#). The medication could still be abused when taken orally, and taking too much of the drug could still result in an overdose, FDA notes. Targiniq ER is part of FDA's ER/LA Opioid Analgesics Risk Evaluation and Mitigation Strategy, which requires companies to provide to health care providers educational programs on safely prescribing ER/LA opioid analgesics, medication guides, and patient counseling documents containing information on the safe use, storage, and disposal of ER/LA opioids.

### **Attorney General Holder Urges Actions by Federal Agencies, Congress to Fight Opioid Abuse and Overdose**

United States Attorney General Eric Holder is urging federal law enforcement agencies to “identify, train and equip personnel who may interact with a victim of a heroin overdose” to carry naloxone, a medication that can reverse an opioid overdose. In a memorandum, Holder also requests that Congress protect enforcement tools, specifically Immediate Suspension Orders, a critical component of Department of Justice efforts to shut down rogue drug sellers and distributors. Seventeen states and the District of Columbia have amended their laws to increase access to naloxone, resulting in over 10,000 overdose reversals since 2001,

### **COMMITTEE REPORTS**

#### Medical Examiner's Report

No report.

#### DEA Report

No report.

#### Substance Abuse Report

No report

#### Law Enforcement Report

No report.

#### Regulatory Committee Report

No report.

#### Legislative Committee Report

No report

### **INSPECTION REPORT**

Mr. Dryden shared a letter from Walmart who is requesting support to adjust their processes to maintain eprescriptions and efaxed prescriptions solely electronically.

### **COMMITTEE CORRESPONDENCE**

None

### **OTHER BUSINESS BEFORE THE BOARD**

Non Photo ID Cards – Amish Residents, Religious beliefs prevent them from having their picture taken. Ms. Kelly asked who was inquiring regarding this issue. Ms. Letitia Kanar, Pharmacy Operations Manager, A I Dupont Children's Hospital stated she had requested this discussion to be put on the agenda. There are concerns regarding the prescribing of controls and the requirement for photo ID to receive controls and the issue of religious beliefs preventing them from having a photo ID. Ms. Kelly reviewed the current regulation's and stated there is no current support to provide an exception to the photo ID requirement. Ms. Kelly stated that a regulatory change would be required to make an exception to the requirement. The option to have another individual who holds photo identification to pick up the prescription is available. The committee asked that this issue remain on the agenda for further discussion.

### **PUBLIC COMMENTS**

None

### **EXECUTIVE SESSION**

No executive session was needed.

### **NEXT SCHEDULED MEETING**

The next regular meeting will be held on September 24, 2014 at 9:00 am at the Buena Vista Conference Center.

### **ADJOURNMENT**

A motion was made by Mr. Von Goerres, seconded by Jankowski, to adjourn the meeting. The motion unanimously carried. The meeting adjourned at 12:15 pm.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Christine Mast".

Christine Mast  
Administrative Specialist III  
Office of Controlled Substances